K121109

KONICA MINOLTA

MAY 23 2012

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo,191-8511, Japan

510 (k) Summary

Date of summary: October 19, 2011

510(k) Owner:
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Device Name and Classification

Trade name	AeroDR X70
Classification name	Stationary X-ray System
Device	RADIOLOGY
Product Code	KPR
Regulation Number	892.1680
Device classification	Class II

Predicate device

The following legally marketed device to which Konica Minolta claims equivalence

1. Intuition manufactured by Arcoma AB, K073632

Device description

The AeroDR X70 is a stationary x-ray system with a ceiling mounted tube support, a floor mounted table and wall stand. The image receptor and the image receptor holder is placed in the table or the wall stand.
The ceiling stand and the table are motorized for up and down movements, all other movements are manually operated.
The standard equipment includes a graphic display showing X-ray tube rotation and film focus or source image distance, a generator control console and an Image system console.

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Intended use
AeroDR X70 is a stationary x-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment.

The AeroDR X70 is not intended for mammography

Comparison of device technological Characteristics
The AeroDR X70 is basically the same product as the predicate device Intuition. Both devices have the ceiling stand and the table motorized for up and down movements, all other movements are manually operated. The Wallstand in both Systems are counter weighted balanced. The AeroDR X70 Wallstand has some modifications in the brake release; the Intuition Wallstand is equipped with manual brake release for the detector holder but the AeroDR X70 brake for the same function is magnetic and operated electrically.

AeroDR X70 digital image system consisting of REGIUS CONSOLE CS-3000 and flat panel AERODR, compared to Intuition image system consisting of CXDI-50G have the same imaging principle, physical characteristic and intended use.

Non Clinical data
The provided performance data demonstrate that the imaging system in the AeroDR X70 system is substantially equivalent to the predicated device with regards to the capability of producing radiographic images of various portions of the human body.

To verify that the subject device is as safe as the predicate device the same scope of testing has been preformed by certification body. The following standards are met to demonstrate the safety of the subject device

Standard	Ver	Description
IEC 60601-1 +A1 +A2	1988	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2	2001	Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-3	1994	General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
IEC60601-1-4 +A1	1996	General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
IEC 60601-2-7	2007	Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators
IEC 60601-2-28	1993	Particular Requirements for the Safety of X-Ray Source Assy. and X-Ray Tube Assy. for Medical Diagnosis
IEC 60601-2-32	1994	Part 2: Particular requirements for the Safety of Associated Equipment of X-ray Equipment
NEMA XR7	1995 (R2000)	High-Voltage X-Ray Cable Assemblies and Receptacles

Clinical data
No clinical data was needed to demonstrate substantial equivalence.

Conclusion
Based on the information in this submission similarity to the predicate device (The Arcoma AB Intuition system) and the results of our design control activities, including sub supplier agreements, it is our opinion that the Konica Minolta AreoDR X70 system described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphic, Inc.
% Mr. Williams Sammons
Technical Reviewer
Intertek Testing Services NA, Inc.
2307 E Aurora Road, Unit B7
TWINSBURG OH 44087

MAY 23 2012

Re: K121109
Trade/Device Name: AeroDR X70
Regulation Number: 21 CFR 872.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 11, 2012
Received: April 12, 2012

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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No.1 Sakura-machi, Hino-shi, Tokyo,191-8511, Japan

Indication for Use

510(k) Number: K121109

Device Name: AeroDR X70

AeroDR X70 is a stationary x-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment. The AeroDR X70 is not intended for mammography

Prescription Use _X__ And/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121109